Package leaflet: Information for the user

Ambrisentan betapharm 5 mg film-coated tablets
Ambrisentan betapharm 10 mg film-coated tablets

Ambrisentan

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ambrisentan betapharm is and what it is used for

Ambrisentan betapharm contains the active substance ambrisentan. It belongs to a group of medicines called other antihypertensives (used to treat high blood pressure).

Ambrisentan betapharm it is used to treat pulmonary arterial hypertension (PAH) in adults. PAH is high blood pressure in the blood vessels (the pulmonary arteries) that carry blood from the heart to the lungs. In people with PAH, these arteries get narrower, so the heart has to work harder to pump blood through them. This causes people to feel tired, dizzy and short of breath.

Ambrisentan betapharm widens the pulmonary arteries, making it easier for the heart to pump blood through them. This lowers the blood pressure and relieves the symptoms.

Ambrisentan betapharm may also be used in combination with other medicines used to treat PAH.

2. What you need to know before you take Ambrisentan betapharm

Do not take Ambrisentan betapharm
- if you are **allergic** to ambrisentan or any of the other ingredients of this medicine (listed in section 6)
- **if you are pregnant**, if you are **planning to become pregnant**, or if you **could become pregnant** because you are not using reliable birth control (contraception). Please read the information under “Pregnancy”

- if you are **breast-feeding**. Read the information under "breast-feeding"
- if you have **liver disease**. Talk to your doctor, who will decide whether this medicine is suitable for you
- if you have **scarring of the lungs**, of unknown cause (idiopathic pulmonary fibrosis)

Warnings and precautions
Talk to your doctor before taking this medicine if you have:

- liver problems
- anaemia (a reduced number of blood cells)
- swelling in the hands ankles or feet caused by fluid (*peripheral oedema*)
- lung disease where the veins in the lungs are blocked (*pulmonary veno-occlusive disease*)

Your doctor will decide whether Ambrisentan betapharm is suitable for you.

<u>You will need regular blood tests</u>
Before you start taking Ambrisentan betapharm and at regular intervals while you are taking it, your doctor will take blood tests to check:

- whether you have anaemia
- whether your liver is working properly

It is important that you have these regular blood tests for as long as you are taking Ambrisentan betapharm.

Signs that your liver may not be working properly include:

- loss of appetite
- feeling sick (nausea)
- being sick (vomiting)
- high temperature (fever)
- pain in your stomach (abdomen)
- yellowing of your skin or the whites of your eyes (jaundice)
- dark-coloured urine
- itching of your skin

If you notice any of these signs: **Tell your doctor immediately.**

Children and adolescents
Ambrisentan betapharm is not recommended for children and adolescents aged under 18 years as the safety and effectiveness is not known in this age group.

Other medicines and Ambrisentan betapharm
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may need to adjust your dose of Ambrisentan betapharmif you start taking cyclosporine A (a medicine used after transplant or to treat psoriasis).

If you are taking rifampicin (an antibiotic used to treat serious infections) your doctor will monitor you when you first start taking Ambrisentan betapharm.

If you are taking other medicines used to treat PAH (e.g. iloprost, epoprostenol, sildenafil) your doctor may need to monitor you.

Tell your doctor or pharmacist if you are taking any of these medicines.

Pregnancy
Ambrisentan betapharm may harm unborn babies conceived before, during or soon after treatment.

If it is possible you could become pregnant, use a reliable form of birth control (contraception) while you are taking Ambrisentan betapharm. Talk to your doctor about this.

Do not take Ambrisentan betapharm if you are pregnant or plannig to become pregnant.

If you become pregnant or think that you may be pregnant while you are taking Ambrisentan betapharm **see your doctor immediately.**

If you are a woman who could become pregnant, your doctor will ask you to take pregnancy test before you start taking Ambrisentan betapharm and regularly while you are taking this medicine.

Breast-feeding
It is not known if Ambrisentan betapharm is transferred to breast milk.

Do not breast-feed while you are taking Ambrisentan betapharm. Talk to your doctor about this.

Fertility
If you are a man taking Ambrisentan betapharm, it is possible that this medicine may lower your sperm count. Talk to your doctor if you have any questions or concerns about this.

Driving and using machines
Ambrisentan betapharm may cause side effects, such as low blood pressure, dizziness, tiredness (see section 4), that may affect your ability to drive or use machines. The symptoms of your condition can also make you less fit to drive or use machines.

Do not drive or use machines if you are feeling unwell.

Ambrisentan betapharm film-coated tablets contains lactose. If you have been told by your doctor that you have an intolerance to some sugars contact you doctor before taking Ambrisentan betapharm.

3. How to take Ambrisentan betapharm

Always take this medicine exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

How much Ambrisentan betapharm to take
The usual dose of Ambrisentan betapharm is one 5 mg tablet, once a day. Your doctor may decide to increase your dose to 10 mg, once a day.

If you take cyclosporine A, do not take more than one 5 mg tablet of Ambrisentan betapharm, once a day.

How to take Ambrisentan betapharm
It is best to take your tablet at the same time each day. Swallow the tablet whole, with a glass of water, do not split, crush or chew the tablet. You can take Ambrisentan betapharm with or without food.

If you take more Ambrisentan betapharm than you should
If you take too many tablets you may be more likely to have side effects, such as headache, flushing, dizziness, nausea (feeling sick), or low blood pressure that could cause light-headedness:

Ask your doctor or pharmacist for advice if you take more tablets than prescribed.

If you forget to take Ambrisentan betapharm
If you forget a dose of Ambrisentan betapharm, just take the tablet as soon as you remember, then carry on as before.

Do not take two tablets at the same time to make up for a forgotten dose.

Do not stop taking Ambrisentan betapharm without your doctor's advice.
Ambrisentan betapharm is a treatment that you will need to keep on taking to control your PAH.

Do not stop taking Ambrisentan betapharm unless you have agreed this with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Conditions you and your doctor need to look out for:

Allergic reactions
This is a common side effect that may affect **up to 1 in 10** people. You may notice a rash or itching and swelling (usually of the face, lips, tongue or throat), which may cause difficulty in breathing or swallowing

Swelling (oedema), especially of the ankles and feet
This is a very common side effect that may affect **more than 1 in 10** people

Heart failure
This is due to the heart not pumping out enough blood, causing shortness of breath, extreme tiredness and swelling in the ankles and legs. This is a common side effect that may affect **up to 1 in 10** people

Anaemia (reduced number of red blood cells)
This is a blood disorder which can cause tiredness, weakness, shortness of breath, and generally feeling unwell. Sometimes this requires a blood transfusion. This is a very common side effect that may affect **more than 1 in 10** people

Hypotension (low blood pressure)
This can cause light-headedness. This is a common side effect that may affect **up to 1 in 10** people

> **Tell your doctor straight away** if you get these effects or if they happen suddenly after taking Ambrisentan betapharm.

It is important to have regular blood tests, to check for anaemia and that your liver is working properly. **Make sure that you have also read the information in section** 2 under 'You will need regular blood tests' and 'Signs that your liver may not be working properly'.

Other side effects include
Very common side effects:
- headache
- dizziness
- palpitations (fast or irregular heart beats)
- worsening shortness of breath shortly after starting Ambrisentan betapharm.
- a runny or blocked nose, congestion or pain in the sinuses
- feeling sick (nausea)
- diarrhoea
- feeling tired

In combination with tadalafil (another PAH medicine)
In addition to the above:
- flushing (redness of the skin)
- being sick (vomiting)
- chest pain/discomfort

Common side effects:
- blurry or other changes to vision
- fainting
- abnormal blood test results for liver function
- a runny nose
- constipation
- pain in your stomach (abdomen)
- chest pain or discomfort
- flushing (redness of the skin)
- being sick (vomiting)

- feeling weak
- nose bleed
- rash

In combination with tadalafil
In addition to the above, except abnormal blood test results for liver function:
- ringing in the ears (*tinnitus*) only when taking the combination treatment.

Uncommon side effects:
- liver injury
- inflammation of the liver caused by the body's own defences (autoimmune hepatitis)

In combination with tadalafil
- sudden hearing loss.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ambrisentan betapharm

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ambrisentan betapharm contains

The active substance is ambrisentan.
Each film-coated tablet contains 5 mg or 10 mg of ambrisenatn.

The other ingredients are: lactose monohydrate, microcrystalline cellulose, pregelatinised maize starch, magnesium stearate, poly vinyl alcohol, titanium dioxide (E171), polyethylene glycol, talc and iron oxide (E172).

What Ambrisentan betapharm looks like and contents of the pack

Ambrisentan betapharm 5 mg film-coated tablet is a pink, circular film-coated tablet with "5" debossed on one side.

Ambrisentan betapharm 10 mg film-coated tablet is a pink oval shaped film-coated tablet with "10" debossed on one side.

Ambrisentan betapharm is supplied as 5 mg and 10 mg film-coated tablets in blister packs of 10, 30 and 120 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

betapharm Arzneimittel GmbH
Kobelweg 95
86156 Augsburg
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:>

France	AMBRISENTAN REDDY PHARMA 5 mg, 10 mg comprimé pelliculé
Germany	Ambrisentan beta 5 mg/-10 mg Filmtabletten
Ireland	Ambrisentan betapharm 5 mg, 10 mg film-coated tablets
Italy	Ambrisentan Dr. Reddy's
Spain	Ambrisentan Dr. Reddys 5 mg, 10 mg comprimidos recubiertos con película EFG
United Kingdom	Ambrisentan Dr. Reddy's 5 mg, 10 mg film-coated tablets

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